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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,513	01/19/2001	James A. Patterson	P-1754	9761

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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/766,513	PATTERSON ET AL.	
	Examiner	Art Unit	
	Frank I Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: Please delete amendment which states that "these two cases being the onlv ones in which James A. Patterson and John A. Thompson are co-inventors". The amendment is incorrect as James a. Paterson and John a. Thompson are co-inventors in US Pat. 6,267,896.

Appropriate correction is required.

The amendment filed 12/11/2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is "6,187,347" which is inserted in pages 3,7 and 12 of the Specification in place of the blank lines. Applicant supports this amendment by indicating that said patent is the only other patent in which Patterson and Thompson are co-inventors, however, as indicated above this is incorrect. Applicant has not provided any other reason which establishes that said US Patent is the US Patent which is described in the Specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for ferrate (VI) salts and hydrophilic proton donor and KMnO4, Na2O2 or

KIO3 in combination with resin which is a hydrophilic proton donor does not reasonably provide enablement for all hydrophilic oxyacid salts or combinations of the same with all hydrophilic proton donors or hydrophilic polymers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The nature of the invention:

The invention is directed to a method of arresting flow of blood from a bleeding wound comprising providing an effective amount of a substantially anhydrous compound of a hydrophilic oxy acid salt combined with an effective amount of a hydrophilic proton donor which will hydrate in the presence of blood to thereby promote clotting of the blood and applying for a sufficient amount of time and a composition combining a hydrophilic oxy acid salt and a hydrophilic polymer material.

The state of the prior art and the predictability or lack thereof in the art:

The prior art of record does discloses hydrophilic oxyacid salts for clotting blood, however, there is also art which indicates that hydrophilic oxy acid salts may be combined with blood or platelets while maintaining viability of the same. See Rubinstein (US Pat. 5,709,992) (Column 4, lines 1-36) (disclosing that chlorine dioxide, sodium tetraborate, sodium perborate, potassium permanganate, sodium persulfate, calcium hypochlorite, potassium chlorate, sodium hypochlorite, sodium chlorate plus lactic acid, salts of hypochlorous acid and chlorous acid, sodium peroxide, alkali perborates may be added to whole blood without substantial loss of physiological activity); Read et al. (US Pat. 5,651,966) (Column 2, lines 41-68) (disclosing a

method of fixing platelets by mixing with potassium permanganate or sodium permangante while retaining the viability of the platelets). As such, it appears that predictability in the art is low.

The amount of direction or guidance present and the presence or absence of working examples:

The specification discloses relatively few examples of oxy acid salts, i.e. ferrate (VI) salts, potassium permanganate, sodium peroxide and potassium iodate, and hydrophilic proton donors and hydrophilic polymer materials, i.e. cationic resins, dessicants, organic acids, acid salts (See Specification, pages 13-15). The working examples appears to be limited to use of ferrate (VI) salts, potassium permanganate, sodium peroxide and potassium iodate with cationic exchange resins (See Specification, pages 13-15).

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that they claim a method of clotting blood and composition for clotting blood using any hydrophilic oxy acid with any hydrophilic polymer or hydrophilic proton donor. As such, in light of the above, it appears that one of ordinary skill in the art would be required to do undue experimentation in order to determine what other oxy acid salts and hydrophilic polymer of hydrophilic proton donor would be suitable for clotting blood.

Claims 5-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No where in the Specification as originally filed is the term "hydrophilic oxyacid salt" disclosed. Although Applicant is correct in asserting that potassium ferrate is soluble in

water, the Specification indicates that when potassium ferrate contacts water in the blood, insoluble FeOOH and Fe2O3 results which act on platelets to release prothrombin (Specification, pg. 6). Further, not all oxy acid salts are soluble in water; for example, iron molybdate and iron chromate (See CRS Handbook of Chemistry and Physics at page 4-65,4-66). As such, Applicant has not shown that one of ordinary skill in art would readily recognize that "hydrophilic oxyacid salts" was what was intended at the time the Application was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-13 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: oxyacid forming insoluble Fe OOH or Fe2O3 or other insoluble compound which lyses platelets to release prothrombin and Fe+++ when combined with blood with respect to the method of using claims and capable of forming insoluble FeOOH or Fe2O3 or other insoluble compound which lyses platelets to release prothrombin and Fe+++ when combined with blood (Specification, pages 6-9).

Claim Rejections - 35 USC §102/ 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fellman (US Pat. 5,232,914).

Fellman expressly discloses a composition containing potassium iodate, anhydrous citric acid, dry polyvinyl pyrrollidine and a composition containing iodine pentoxide or potassium iodate, ascorbic acid and solid polyvinyl alcohol or polyvinyl pyrrolidone dessicant falling within the scope of applicant's claims (Column 6, lines 15-20, Claims 1-10).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products that contain the same exact ingredients/components as that of the claimed invention. See In re Fitzgerald, 205 USPQ 594 (CCPA 1980). See also In re May, 197 USPQ 601, 607 (CCPA 1978).

Claims 7-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over JP 7-177842.

JP 7-177842 expressly discloses the combination of calcium oxide and an organic acid solidifies blood and that addition of the organic acid increases the activity of the calcium oxide (paragraphs 0034-0043) falling within the scope of applicant's claims.

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products that contain the same exact ingredients/components as that of the claimed invention. See In re Fitzgerald, 205 USPQ 594 (CCPA 1980). See also In re May, 197 USPQ 601, 607 (CCPA 1978).

Claims 5-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olson et al. (U.S. Pat. 2,491,416) in view of Leveen et al., Burgeni et al., Eberl et al., Masci et al., US Pat. 2,532,358 and Micelli et al. for the reasons set forth in the prior Office Actions in further view of JP 7-177842 and the further reasons below.

Olson et al., Leveen et al., Burgeni et al., Eberl et al. and Masci et al. US Pat. 2,532,358 and Micelli et al. were discussed in the prior Office Action and the same are incorporated herein.

JP 7-177842 teaches that the combination of calcium oxide and an organic acid solidifies blood and that addition of the organic acid increases the activity of the calcium oxide (paragraphs 0034-0043).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Applicant argues that the claimed composition is hydrophilic whereas the tantalum oxide is hydrophobic. Examiner accepts Applicant's arguments that iron oxide and tantalum oxide are insoluble in water. However, Applicant's claims do not exclude the use of insoluble compounds. In fact, the Specification as indicated above indicates that the formation of insoluble compounds is required. With respect to calcium chloride, Applicant does not appear to address this issue only indicating that the rejection is a moot issue. However, the rejection is not a moot issue as alkaline salts are specifically claimed to be one of the compounds chosen as oxyacids or hydrophilic proton donors. Further, the prior art above discloses the combination of calcium oxide, which is water soluble, with organic acids, i.e. a hydrophilic proton donor, which is used to solidify blood. As such, one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that calcium oxide, which is an alkaline metal oxide,

with organic acid, which is a hydrophilic proton donor, with the expectation that blood would be clotted by the same. .

The declaration of Goodman under 37 CFR 1.132 filed 12/11/2003 is insufficient to overcome the rejection of claims 5-13 because of the following: Applicant argues that the declaration supports a finding of long felt need. However, there is no showing that others of ordinary skill in the art were working on the problem and if so, for how long. In addition, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem. Applicant argues that the affidavit sets forth numerous competitors (but only five alleged competitors are listed and there is no evidence showing that they are in fact competitors in Applicant's market or that they sell similar products) which if the present invention has been obvious they would surely have marketed a similar product in light of Applicant's gross sales of its products. There are numerous reasons why a competitor may or may not implement marketing of a similar product, the fact that Applicant has derived an alleged commercial success from a product and its alleged competitors have allegedly not marketed a similar product, does not make the claims any less obvious. See MPEP §§ 716.03, 716.04.

Gross sales figures do not show commercial success absent evidence as to market share, Cable Electric Products, Inc. v. Genmark, Inc., 226 USPQ 881 (Fed. Cir. 1985), or as to the time period during which the product was sold, or as to what sales would normally be expected in the market, Ex parte Standish, 10 USPQ2d 1454 (Bd. Pat. App. & Inter. 1988).

Evidence of commercial success must be commensurate in scope with the claimed invention. See MPEP 716.03(a). Examiner is unable to determine from the affidavit whether or

not this requirement has been met as there is no indication what was contained in the product sold which allegedly led to the alleged gross sales.

The affidavit refers to exhibit B, but no exhibit B is attached.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached at (571)272-0602). Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at ~~(703) 308-1235 and (703) 308-0198, respectively.~~ (571) 272-1600

FIC
March 17, 2004

JOHN PAK
PRIMARY EXAMINER
GROUP 1600